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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP.,	:	
Plaintiff,	:	**OPINION**
v.	:	Civ. No. 05-897 (WHW)
ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,	:	
Defendants.	:	

Walls, Senior District Judge

Presently before the Court is a motion by defendants Zimmer, Inc.'s, Zimmer Austin, Inc.'s, and Smith & Nephew, Inc.'s joint motion for summary judgment on the issues of non-infringement and invalidity on claims 3, 6, 7, 10, 11 and 12 of the U.S. Patent No. 6,818,020 ("the '020 patent"). On the issue of non-infringement, defendants argue that their products lack an essential element in each of the patent claims at issue, namely, a "***non-increasing*** oxidation index" upon oven-aging the products at 80^{N}C for at least 11 days in air. On the issue of invalidity, defendants argue that because plaintiff chose to use the words "non-increasing" and "does not increase" without equivocation in the patent claims, plaintiff cannot argue that "does not increase" means "increase but not by much." This contradictory interpretation would render

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the claim invalid because then the term "***non-increasing*** oxidation index" is indefinite.

Having considered the parties' written submissions and oral arguments, the Court denies the defendants' joint motion for summary judgment on both issues.

I. FACTS AND PROCEDURAL HISTORY[1]

Howmedica is a New Jersey corporation with its principal place of business in Mahwah, New Jersey that manufactures and markets medical implants such as artificial knee and hip implants. Starting in 1993, Howmedica filed a series of related patents that described processes for heating and irradiating polymers used in medical implants. The patents describe processes where a polymer is first irradiated, which causes free radicals to form. The polymer is then heated, which increases the oxidation resistance of the plastic by causing cross-links to form between free radicals produced by the polymer's irradiation. A polymer with greater oxidation resistance retains its physical properties better, which in turn makes it more suitable for use in medical implants because it deteriorates more slowly in the body.

Defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. (collectively the "defendants") are also corporations in the business of manufacturing and marketing medical implants. In February 2005, Howmedica brought this action against the defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to

[1] Additional factual background is recounted in the Court's June 13, 2007 Opinion whereby the Court granted defendants' motion for summary judgment on invalidity of the U.S. Patent No. 6,174,934, U.S. Patent No. 6,372,814, and U.S. Patent No. 6,664,308. This opinion will include only facts pertinent to the disposition of the present motion for summary on the remaining patent, the '020 patent.

polymeric materials used in medical implants. These four patents are U.S. Patent No. 6,174,934 (filed Jan. 23, 1998) ("the '934 patent"); U.S. Patent No. 6,372,814 (filed June 28, 2000) ("the '814 patent"); U.S. Patent No. 6,664,308 (filed Jan. 8, 2002) ("the '308 patent"); U.S. Patent No. 6,818,020 (filed June 13, 2003) ("the '020 patent") (collectively, "the patents-in-suit"). Howmedica claims that four of the defendants' products, Longevity, Prolong, Durusul, and XLPE, infringe these patents.

On July 21, 2006, defendants filed their first joint motion for summary judgment on three of the four patents: the '934 patent, the '814 patent and the '308 patent. On April 23, 2007, the Court issued its Markman Order construing the claim terms and phrases needing construction as identified by the parties. On May 15, 2007, the parties argued the first motion for summary judgment. On June 13, 2007, the Court granted defendants' joint motion for summary judgment on the issue of invalidity as to the '934 patent, the '814 patent and the '308 patent. The Court did not consider defendants' motion for summary judgment on non-infringement on these three patents because this issue became moot.

On May 4, 2007, the defendants filed their second joint motion for summary judgment on the remaining patent, the '020 patent. The '020 patent is a continuation of application No. 10/041,118, now the '308 patent, which is a continuation of application No. 09/604,868, now the '814 patent, which is a continuation of application No. 09/012,345, now the '934 patent. All four patents share the same specification.

All the claims at issue in this motion for summary judgment have a similar claim limitation requiring that the claimed invention have a "non-increasing FTIR oxidation index," an

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"FTIR oxidation index which does not increase," or "a non-increasing FTIR oxidation index of 0.01 [or less]" with oven aging in air at 80°C for 11 days (collectively the "non-increasing oxidation index" claim limitation). (SOF 567; Ex. A, '020 Patent, col. 12.)

Table 1: Claims at Issue in Motion for Summary Judgment

Claim No.	Claim Language
3	The medical implant as set forth in claim 1 wherein the polyethylene has a FTIR (Fourier Transform Infra-red Spectroscopy) **oxidation index which does not increase** with oven aging in air at 80^{N} C. for up to 11 days.
6	A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 wherein the level of free radicals is $1.0x10^{17}$ /gram or less and an **oxidation index which does not increase** during oven aging in air at 80^{N} C. for 11 days.
7	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at temperature greater than 25°C. for a sufficient time to have a solubility of less than 80.9% in trichlorobenzene and a **non-increasing FTIR oxidation index** during oven aging in air at 80^{N} C. for up to 11 days.
10	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25°C. for a sufficient time to have a level of free radicals of $1.0x10^{17}$ /gram or less and an **oxidation index which does not increase** during oven aging in air at 80^{N} C. for 11 days.
11	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25°C. for a sufficient time to have a **non-increasing FTIR oxidation index** of 0.01 during oven aging in air at 80^{N} C. for 11 days.

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12	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25°C. for a sufficient time to have a **non-increasing ETIR oxidation index** of 0.01 or less during oven aging in air at 80^{N} C. for 11 days and a solubility of less than 80.9% in trichlorobenzene.

('020 Patent, col. 12.) On April 23, 2007, the Court decided the Markman motions and construed the term "oxidation index" to mean a ratio which is derived from the spectroscopic measurements described by the specification. However, neither party requested the Court to construe the meaning of the terms "non-increasing" and "does not increase" as these terms relate to the term "oxidation index."

The term "non-increasing oxidation index" is the subject of defendants' attack on the validity of the '020 patent because the term is indefinite and defendants' defense against non-infringement because defendants' products lack a "non-increasing oxidation index" upon aging their products at 80°C for at least 11 days in air. Defendants move for summary judgment on both issues.

II. SUMMARY JUDGMENT STANDARD

The same summary judgment standard applies to motions involving patent claims as it applies to motions involving other types of claims. See, e.g., Becton Dickinson & Co. v. C.R. Bard. Inc., 922 F.2d 792, 795-96 (Fed. Cir. 1990); Avia Group Int'l, Inc. v. L.A. Gear Calif., Inc., 853 F.2d 1557, 1560-61 (Fed. Cir. 1988). Summary judgment is appropriate when the moving party establishes that "there is no genuine issue as to any material fact and that [it] is entitled to a

judgment as a matter of law." Fed. R. Civ. P. 56(c). Only a genuine and material factual dispute between the parties will defeat a motion for summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is genuine if a reasonable jury could find for the non-moving party on that issue. It is material if, under the substantive law, that issue would affect the outcome of the suit. See id. at 248.

A court must enter summary judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The party moving for summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record]" that show that there is no genuine material issue of fact as to the non-existence of that element. Id. at 323. When the burden of proof for a particular factual element falls on the non-moving party, the moving party must initially demonstrate that the non-moving party cannot meet its burden with the evidentiary material of record admissible at trial. See id. at 322-23.

Once the moving party has carried its burden under Rule 56, "its opponent must do more than simply show that there is some metaphysical doubt as to the material facts in question." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). To survive a motion for summary judgment, a non-movant must present more than a mere scintilla of evidence in his favor. Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). The opposing party must set forth specific facts showing a genuine issue for trial and may not rest upon the mere allegations or denials of its pleadings. Shields v. Zuccarini, 254 F.3d 476, 481 (3d

Cir. 2001).

At the summary judgment stage the court's function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. See Anderson, 477 U.S. at 249. In so doing, the court must construe the facts and inferences in the light most favorable to the non-moving party. Bartnicki v. Vopper, 200 F.3d 109, 114 (3d Cir. 1999).

III. DISCUSSION

A. Motion for Summary Judgment on Invalidity

1. Legal Standard for Invalidity Based on Indefiniteness

The determination of whether a particular patent claim is "invalid for indefiniteness presents a question of law." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001). This is because "claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Personalized Media Commc'ns, L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998). Indefiniteness remains a matter of law, and the proper province of the court, even when determining whether a claim is indefinite depends on an underlying issue of fact. Exxon, 265 F.3d at 1376. In such circumstances the court will consider those underlying factual issues, and rule on indefiniteness as a "matter of law on summary judgment." Id.

35 U.S.C. § 112 states that for a patent claim to be valid, it must be definite:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his

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invention.

The statute requires definiteness to foster invention; vague claims would deter inventors by confronting them with an undue risk of infringement. See United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942) ("statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."); Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342 (Fed. Cir. 2005) (quoting United Carbon). According to the Federal Circuit, a claim is sufficiently definite to satisfy section 112 "[i]f one skilled in the art would understand the bounds of the claim when read in light of the specification." Miles Labs., Inc., v. Shandon, Inc., 997 F.2d 870 (Fed. Cir. 1993). Courts do not require a patent claim be absolutely clear to be valid. They only require "that the claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite." Exxon, 265 F.3d at 1375.

For any patent approved by the United States Patent & Trademark Office (the "PTO"), there is a "statutory presumption of validity." Exxon, 265 F.3d at 1375. The burden of proving a patent's invalidity rests with the party that challenges its validity. See 35 U.S.C. § 282. To meet that burden, the party challenging validity bears the burden of proving, by clear and convincing evidence, that the invention fails to meet the requirements of patentability. See Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the

truth of [the] factual contentions [is] 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

In Pfizer, Inc. v. Apotex, Inc., the Federal Circuit explained the different burdens between the patentee and the party changing the patent's validity. 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). "[O]nce a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence." Id. at 1360. The patentee need not submit evidence to support the conclusion that its patent remains valid, but "once a challenger introduces evidence that might lead to a conclusion of invalidity-what we call a prima facie case-the patentee 'would be well advised to introduce evidence sufficient to rebut that of the challenger.'" Id. (quoting Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed. Cir. 1986)). The district court's responsibility is to determine whether the challenging party "has met its burden by clear and convincing evidence by considering the totality of the evidence, including any rebuttal evidence presented by the patentee." Pfizer, 480 F.3d at 1360.

2. Analysis of the Issue of Invalidity

Defendants advance two bases why the claims are indefinite. First, they argue that the patent specification fails to adequately inform one of ordinary skill in the art what the term "non-increasing oxidation index" means. Because plaintiff chose to draft the claim language without equivocation (such as "substantially non-increasing" or "essentially non-increasing"), defendants argue that "non-increasing" simply means that a sample of the ultra-high molecular weight polyethylene material ("UHMWPE") exhibited no measurable, positive increase in the oxidation index when oven-aged in air at 80°C for 11 days. Defendants argue that as a matter of patent

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law, plaintiff's contradictory construction that "non-increasing" means "increasing but not by much" renders the term indefinite.

Plaintiff rejects defendants' argument that "non-increasing" requires mathematical absoluteness and argues that the term "non-increasing" would be understood by one of ordinary skill in the art to include insignificant increases in the oxidation index. Dr. Stephen Li, Ph.D., the president of Medical Testing and Innovations LLC, who is qualified as one of ordinary skill in the art, testified that increases in the oxidation index are relative and that "a change in oxidation index values of 0.01 is not a change in oxidation index." (Li. Decl., at ¶ 32.) Plaintiff also directed the Court's attention to the testimony of defendants' witness, Dr. Ray A. Gsell, who manages defendant Zimmer's chemical research lab. Dr. Gsell testified in his deposition that measuring changes in the oxidation indices in the thousandths is unrealistic and measuring changes in the hundredths "is sort of pushing it":

> In reality, those oxidation index measurements probably aren't–you aren't able to have significant digits more than–well, even two places after the decimal is sort of pushing it, but typically we write, you know, .0, .XY, but once you get to the third, fourth, fifth, you're in–you're just–it's not realistic.

(Plaintiff's Ex. AA, Gsell Dep. Tr., at 101: 3-9.) Because both plaintiff's expert and defendants' witness testified that changes in the hundredths are relatively insignificant, one of ordinary skill in the art would interpret the term "non-increasing" to include insignificant increases.

During oral arguments, the Court had asked defendants' counsel why they did not provide expert testimony as to what one of ordinary skill in the art would understand the term "non-increasing" to mean. Defendants' counsel argued that claim indefiniteness is a matter of law and as a matter of law, plaintiff's proposed construction would contradict the plain meaning of the

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term "non-increasing." Defendants' counsel did not see the necessity for providing expert testimony to aid the Court in understanding the term. The more fatal point is that defendants did not provide expert testimony to rebut their own witness, Dr. Gsell, whose testimony corroborated the testimony of plaintiff's expert, Dr. Li. See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1558 (Fed. Cir. 1983)(where there was "no testimony that those values [specific gravity values] were not known to persons of ordinary skill in the art or could not be calculated or measured," there was no support for the conclusion that "specific gravity of the solid polymer" was indefinite).

The oxidation index, which the Court construed as a ratio which is derived from the spectroscopic measurements described by the specification, are given values in the hundredths. By providing oxidation indices of the UHMWPE samples in the hundredths, the patent specification contemplates that the measurement for the oxidation index should have a mathematical precision in the hundredths. ('020 patent, col. 8, ln. 18-32.) The patent specifiction also provides that the "initial oxidation index" of the "UHMWPE sample irradiated in nitrogen (Method C)" was "0.01, which was not significant." ('020 patent, col. 8, ln. 40-44.)

Although the term "non-increasing" may not be absolutely precise, its imprecision does not render automatically the claim invalid for indefiniteness. BJ Services Co. v. Halliburton Energy Services, Inc., 338 F.3d 1368, 1372 (Fed. Cir. 2003) ("Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid"). Whether "non-increasing" is definite depends on whether one of ordinary skill in the art would understand the term in light of the

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specification. Id. The Court finds that the term "non-increasing oxidation index" to be definite and to include insignificant increases in the oxidation index when a sample of UHMWPE is oven-aged in air at 80°C for 11 days because both Dr. Li and Dr. Gsell, persons of ordinary skill in the art, understood the term this way. John Mezzalingua Assocs., Inc. v. Arris Intern., Inc., No. 03-C-353-C, 2003 WL 23282752, at *7-8 (W.D. Wis. Nov. 14, 2003) ("one of ordinary skill in the art would understand the terms 'non-tapered' and 'constant diameter' to include not only the perfect manifestations of these terms, but also objects that are as close to perfection as available technology can reasonably achieve . . . one of ordinary skill in the art would know that cable connectors are manufactured in the real world and not in the mind of God."). And that is the present, parallel circumstance. To repeat, perfection in this human technology is absent. Persons of ordinary skill in this art recognize that. It follows then that "non-increasing oxidation index" must subsume insignificant increases in that index.

Second, defendants argue that patent specification does not provide a method of deriving the spectroscopic measurements necessary to determine the oxidation index. As to the second basis for indefiniteness, defendants point to three separate times when plaintiff tested defendants' products and obtained three completely different results, despite having used the same calculation method twice.

Between the plaintiff's and defendants' submissions on this motion for summary judgment, four tables of test results measuring the changes in oxidation index of samples of defendants' products when oven-aged at 80^{N}C for at least 11 days in air were provided to the Court and are reproduced below. The test results show various degrees of increases in the

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oxidation indices. The magnitude of increases also vary among the different test results. Defendants argue that these increases in oxidation indices are significant and the differences of the increases among the test results are significant. These significant differences indicate the '020 patent's failure to clearly define a method of deriving the spectroscopic measurements necessary to determine the oxidation index. By not providing a clear method, the patent claims are indefinite.

Table 2: Howmedica's 2005 FTIP Oxidation Index Testing - Method 1

Zimmer's Product Accused of Infringement	Oxidation Index Unaged	Oxidation Index Aged, at 80^{N}C for 11 days
Zimmer Longevity (labeled C)	0.000	0.017
Zimmer Durasul (labeled D)	0.000	0.015
Smith & Nephew XLPE (labeled A)	0.000	0.013

Table 3: Howmedica's 2005 Re-Calculated Oxidation Index Testing - Method 2

Zimmer's Product Accused of Infringement	Oxidation Index Unaged	Oxidation Index Aged, at 80^{N}C for 11 days
Zimmer Longevity	0.000	0.811
Zimmer Durasul	0.000	0.729
Smith & Nephew XLPE	0.000	0.499

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Table 4: Howmedica's 2006 Surface Oxidation Index Testing

Accused Product	Specimen	Oxidation Index Unaged	Oxidation Index Aged, 11 Days
Longevity	C1X1A	0.000	0.003
	C1X1B	0.000	0.000
	C1X1C	0.000	0.000
Durasul	D1X1A	0.000	0.008
	D1X1B	0.000	0.000
	D1X1C	0.000	0.003
Prolong #1	A1X1	0.000	0.000
	A1X2	0.000	0.032
	A1X3	0.000	0.029
Prolong #2	B1X1	0.000	0.000
	B1X2	0.000	0.000
	B1X3	0.000	0.000
XLPE	A1X1A	0.000	0.000
	A1X1B	0.000	0.008
	A1X1C	0.000	0.006

Table 5: Howmedica's 2006 "Average" Oxidation Index Testing

Accused Product	Specimen	Oxidation Index Unaged	Oxidation Index Aged, 11 Days
Longevity	C1X1A	0.000	0.000
	C1X1B	0.000	0.000
	C1X1C	0.000	0.000

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Durasul	D1X1A	0.000	0.000
	D1X1B	0.000	0.000
	D1X1C	0.000	0.000
Prolong #1	A1X1	0.000	0.000
	A1X2	0.000	0.020
	A1X3	0.000	0.010
Prolong #2	B1X1	0.000	0.000
	B1X2	0.000	0.002
	B1X3	0.000	0.000
XLPE	A1X1A	0.000	0.000
	A1X1B	0.000	0.000
	A1X1C	0.000	0.000

In the Court's April 23, 2007 Markman Opinion, the Court construed the term "oxidation index" to mean a ratio which is derived from the spectroscopic measurements described by the specification. Example 1 in the '020 patent specifies a method for determining the oxidation index:

> Two sets of 1-mm-thick UHMWPE sheets prepared by Methods A through D above were oven aged in air at 80^{N}C for 11 and 23 days respectively. After these sheets were cooled in room temperature, a thin specimen of about 100 microns in thickness was cut from each of the 1-mm-thick aged UHMWPE sheets and placed in an IR window for a standard FTIR (A Nicolet 710 FTIP system was used) transmission run. A total of 32 spectra (scans) was collected and averaged. To determine the extent of oxidation, the IR absorption peaks in the frequency range of between 1660 and 1800 cm.sup.-1, corresponding to carbonyl (C--O) functional groups, were integrated for the peak area. The peak area is proportional to the amount of oxidized UHMWPE in the specimen. To correct for difference in specimen thickness, the integrated peak area was then normalized to the specimen thickness, by dividing by the area of the

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> 1463 cm.sup.-1 (methyl) peak which is proportional to the specimen thickness. The obtained ratio was defined as oxidation index.

'020 patent, col. 7, ln. 63 - col. 8, ln. 13. The 2005 and the 2006 test results were determined according to this method described in the patent specification. (SOF 657-684, 719-756.)

The Court finds that the patent clearly specifies a method for deriving the spectroscopic measurement for the oxidation index. Defendants' argument that the differences between test results are significant is as flawed as their argument that "non-increasing" should be read in absolute mathematical terms. Dr. Gsell also testified where the oxidation indices are low, the measurements of the oxidation indices one place beyond the decimal are de minimus:

> my feeling is that oxidation indices should not be reported to more than two decimal places, and even the second one is sort of pushing it. But for the materials that we commonly use this measurement for, the indices are so low that if you only report one place after the decimal, they are all zero.

(Plaintiff's Ex. AA, Gsell Dep. Tr., at 102:3-8). The corollary to Dr. Gsell's statement is that changes in the oxidation indices in the same magnitude would be de minimus. The Court disagrees with defendants' position that the differences in test results are so significant that it would render the patent claims indefinite for failing to provide a method of deriving the spectroscopic measurements necessary to determine the oxidation index.

Accordingly, the Court finds that the term "non-increasing oxidation index" is definite. Defendants' motion for summary judgment as to the issue of invalidity is denied.

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B. Motion for Summary Judgment on Non-infringement

1. Legal Standard for Infringement

The determination of patent infringement is a two-step process: "first, the scope of the claims are determined as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1323 (Fed. Cir. 2002); accord, e.g., CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1365 (Fed. Cir. 2002). "[S]ummary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999).

The plaintiff has the burden of proof on infringement at trial. To prove infringement of a patent claim at trial, the plaintiff must prove by a preponderance of evidence that "every limitation of the patent claims asserted to be infringed is found in the accused device, either literally or by an equivalent." SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted); IMX, Inc. v. LendingTree, LLC, 469 F. Supp. 2d 203, 210-11 (D. Del. 2007).

The defendant's burden at summary judgment is to file a "motion stating that the patentee had no evidence of infringement and [to point] to the specific ways in which accused systems did not meet the claim limitations." Exigent Technology, Inc. v. Atrana Solutions, Inc., 442 F.3d

1301, 1309 (Fed. Cir. 2006). Once the defendant has done this the burden shifts to the plaintiff, who must in turn present some evidence of infringement to the court. Id. at 1309. "Summary judgment of noninfringement is . . . appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial." TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1369-70 (Fed. Cir. 2002).

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). The doctrine of equivalents functions to avoid placing the patentee "at the mercy of verbalism" and to avoid "subordinating substance to form." Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607-08 (1950). The determination of infringement under the doctrine of equivalents requires:

> a showing that the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method.

Aquatex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007). This test also must be determined "against the context of the patent, the prior art, and the particular circumstances of the case." Warner-Jenkinson, 520 U.S. at 24-25.

2. Analysis of the Issue of Non-infringement

Defendants' argument for non-infringement is similar to their argument for

indefiniteness, namely, that plaintiff's test results conclusively show that defendants' products when oven-aged at 80°C for at least 11 days exhibit significant increases in the oxidation index. Because the claim limitation literally requires no increases in the oxidation index, defendants' products lack an essential element in each of the patent claims at issue; thus, their products do not literally infringe the '020 patent. Furthermore, the increases are significant enough to fall outside the purview of patent infringement under the doctrine of equivalents.

For the same reasons that the Court rejected defendants' position on indefiniteness, the Court rejects defendants' position on non-infringement. As stated, the Court does not interpret the term "non-increasing" to require mathematical absoluteness. The Court understands that the Federal Circuit teaches the district courts to take a pragmatic approach when interpreting claim terms. See SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1322 (Fed. Cir. 2006) ("Claim construction is a fact-dependent, invention-oriented exercise in logic and law. It requires judicial awareness that patent claims are directed to inventions which come in great variety. There is no need for judges to create one-type-fits-all pigeonholes for claims . . ."). Even Dr. Gsell, who manages defendant Zimmer's chemical research lab where Zimmer conducts oxidation testing, confirmed that even though two oxidation indices may be different and show a mathematical difference, the two oxidation indices are considered pragmatically the same:

> Q. So then based on these measurements, you can't say that there is really any difference in the oxidation index measured for the non-aged Longevity sample at GN [0.0064] and the accelerated aged Longevity sample at GA [0.0052], . . .
>
> A. Yeah. I would say there is no difference between the results, yeah.

(Plaintiff's Ex. AA, Gsell Dep. Tr., 102: 22 - 103: 3.) Defendants have not provided any expert testimony why the Court should not adopt defendants' own witness's understanding of how measurements of changes in the oxidation index should be read by one of ordinary skill in the art.

The first step in analyzing patent infringement requires the Court to construe the claim term "non-increasing oxidation index." Because neither Dr. Gsell nor Dr. Li, plaintiff's expert, take an absolutist approach to the term "non-increasing," the Court will adopt an ad hoc construction of this term with one qualification.

Defendants correctly point out that the patentee conceded what may be a significant increase in the oxidation index. Howmedica submitted a declaration under 37 C.F.R. § 1.132 by Dr. Shi-Shen Yau, the principal engineer of the Advanced Implant Technology Department of Howmedica Osteonics Corporation, to the PTO in the patent application 10/935,510. The 10/935,510 application is a divisional application of the '020 patent (application 10/461,636). Both the 10/935,510 application and the '020 patent share the same patent specification. The Federal Circuit has authorized district courts to consider statements made by the patentee in subsequent related application in the district courts' claim construction of the patent claims at issue. In Microsoft Corp. v. Multi-Tech Systems, Inc., the Federal Circuit explained:

> Any statement of the patentee in the prosecution of a related application as to the scope of the invention would be relevant to claim construction, and the relevance of the statement made in this instance is enhanced by the fact that it was made in an official proceeding in which the patentee had every incentive to exercise care in characterizing the scope of its invention. Accordingly, we conclude that Multi-Tech's statements made during the prosecution of the '627 patent with regard to the scope of its inventions as disclosed in the common specification are relevant not only to the '627 and '532 patents, but also to the earlier issued '649 patent.

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357 F.3d, 1340, 1350 (Fed. Cir. 2004) (emphasis added). The Court will consider Dr. Yau's declaration and the patent examiner's notice of allowance in construing the term "non-increasing."

Defendants argue that Dr. Yau testified that a difference of 0.01 in the oxidation index is significant and outside the scope of the patent claim. Defendants quote Dr. Yau as stating:

> The difference in measured oxidation index between sample A [which reports an oxidation index of 0.02] and others [which report oxidation indices of 0.01] is statistically significant.

(Dkt. 172, Def.'s Reply, at 8 (citing Def.s' Ex. 114, Dr. Yau's 37 C.F.R. § 1.132 Decl., at 3).) The Court rejects this argument because Dr. Yau was describing the difference in pre-aging oxidation indices of the samples. Table 6 (below) illustrates the change in oxidation index before and after aging in samples A through F.

Table 6: Howmedica's 2/22/07 Submission to the PTO

Sample	Treatment	Oxidation Index	
		Before Aging	After Aging
A	25 kGy gamma irradiation in air	0.02 ± 0.00	0.16 ± 0.01
B	25 kGy gamma irradiation in nitrogen, No anneal	0.01 ± 0.00	0.14 ± 0.00
C	25 kGy gamma irradiation in nitrogen, annealed at 40^{N}C for 2 hours	0.01 ± 0.00	0.11 ± 0.00
D	25 kGy gamma irradiation in nitrogen, annealed at 60^{N}C for 2 hours	0.01 ± 0.00	0.09 ± 0.00
E	25 kGy gamma irradiation in nitrogen, annealed at 80^{N}C for 2 hours	0.01 ± 0.00	0.03 ± 0.00

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F	25 kGy gamma irradiation in nitrogen, annealed at 50^{N}C for 144 hours	0.01 $\pm$ 0.00	0.01 $\pm$ 0.00

The patent claims at issue concern "non-increasing oxidation index" with oven aging in air at 80°C for 11 days. ('020 Patent, col. 12.) Defendants' argument is not on point.

Nevertheless, the Court notes that Dr. Yau provides a clear example of when the oxidation index of a sample exhibits a significant increase. Dr. Yau stated that:

> There was no change in measured oxidation index in sample F that received 80^{N}C aging treatment for 11 days. All other samples (A through E) showed significant increase ($p = 0.001$) in oxidation index.

(Def.s' Ex. 114, Dr. Yau's 37 C.F.R. § 1.132 Decl., at 4) (emphasis added.) Furthermore, the patent examiner referenced the above table when she explained her reasons for allowance of the patent claims:

> The comparative data in Table 1 shows that the ***oxidation index does not increase*** with oven aging at 80°C for 11 days after the irradiation and heating when the heating time and temperature are as set forth in the instant claims. Comparative samples C, D, and E are representative of the heating times and temperatures taught by Streicher et al and show ***an increase in oxidation index*** after the same aging conditions.

(Def.s' Ex. 114, Application 10/935,510, Notice of Allowance, at 2) (emphasis added.) Sample E, which exhibited smaller increases than sample C and D, had an oxidation index of 0.01 $\pm$ 0.00 before aging and 0.03 $\pm$ 0.00 after aging. Both Dr. Yau and the patent examiner considered this difference in the oxidation index (0.02 $\pm$ 0.00) of Sample E as a significant increase in oxidation index.

Accordingly, the Court will consider an increase of 0.02 as a significant increase and to

be outside the scope of the patent claim. However, the Court will refrain from defining with mathematical precision what magnitude of an increase in the oxidation index is insignificant and, thus, falls within the scope of the patent claim. The Court finds that whether an increase in the oxidation index is insignificant to fall within the scope of the patent claim is an issue of fact to be determined on an ad hoc basis.

The Court finds that plaintiff's test results create a genuine issue of whether defendants' products infringe the '020 patent claims. Defendants' motion for summary judgment on the issue of non-infringement is denied.

IV. CONCLUSION

The Court finds that the claim term "non-increasing oxidation index" to be definite and understood by one of ordinary skill in the art. Because this term does not require absolute mathematical precision, the Court will construe this term on an ad hoc basis. Accordingly, defendants' motion for summary judgment on both issues of invalidity and non-infringement are denied.

January 2, 2008

s/William H. Walls
United States Senior District Judge